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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,718	03/01/2002	Kishan Khemani	16096.6	7476

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EXAMINER

WOODWARD, ANA LUCRECIA

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,718

Applicant(s)

KHEMANI ET AL.

Examiner

Ana L. Woodward

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 6, 2005
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 3-5, 13, 14, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-5 do not have express antecedent basis for “inorganic” filler particles.

In claim 13, it is unclear as to whether or not the term “non-biodegradable” also qualifies the “fibers”.

In claim 28, it is unclear as to what is meant by the awkward language “after being formed to a separately-formed substrate”.

Claim Rejections - 35 USC § 102/103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 16-23 and 31-33 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. 6,838,403 (Tsai et al).

Tsai et al disclose breathable biodegradable laminates including a film comprising a biodegradable polymer and up to about 70% by weight of an organic or inorganic filler (column 4, lines 22-67). The filler material creates a microporous structure in the film, which imparts breathability thereto. Furthermore, the films may be stretched and embossed to further enhance their breathability (column 5, lines 13-38). When stretched, the biodegradable polymer portions of the film move away from the filler materials. The filler materials can range up to 50 microns in size. The examples provide various filled biodegradable films comprising a biodegradable polymer and filler particles, which meet the requirements of the present claims both in terms of the types of materials added and their contents. The films are stretched and embossed.

It is reasonably believed that the particle filled-biodegradable films of Tsai et al would necessarily possess dead-fold properties due to the presence of the particulate fillers and the processing techniques used to manufacture them. As to claims 31-33, it is reasonably believed that at least some of the filler particles would protrude from the surface of the sheet due to the orientation process, which causes cavitation and localized separation between the polymer matrix and individual filler particles. The onus is shifted to applicants to establish that the product of the present claims are not the same as or obvious from those set forth by Tsai et al.

Claim Rejections - 35 USC § 103

5. Claims 1-15, 24-28 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0098341 A1 (Schiffer et al) in view of US 6,096,809 (Lorcks et al).

Schiffer et al disclose biodegradable breathable monolayer films (and laminates therefrom) formed by mixing biodegradable polymers or mixtures thereof with a particulate filler, forming the mixture into a film, and stretching the film uniaxially or biaxially to cause voids to form around the filler particles. Suitable biodegradable polymers include polylactic acid, reading on the presently claimed stiff polymer, and other polymers such as polycaprolactone, copolyesters ECOFLEX and EASTAR, etc., reading on the presently claimed soft polymer (page 2, paragraph 0024). The filler particles comprise organic as well as inorganic fillers, reading on the presently claimed filler particles (page 3, paragraphs 0027-0032) and constitute about 5-80% by weight of the breathable film, fulfilling present claims 3-5 (page 2, paragraph 0026). After stretching, the films have a thickness of about 5-50 microns (about 0.0002-0.002 inches), fulfilling present claims 9-11 (page 3, paragraph 0034). The films have a water vapor transmission rate of at least about 500 g/m²/day, as required by present claim 12 (page 4, paragraph 0038). The use of non-biodegradable polymers, as required by present claim 13, is also disclosed (page 3, paragraph 0028). Schiffer et al disclose, as suitable fillers, starch materials that do not appear to contain plasticizers (page 3, paragraph 0029).

In essence, the disclosure of Schiffer et al differs from the above-rejected claims in not expressly exemplifying a combination of stiff and soft thermoplastic biodegradable polymers having the claimed glass transition temperatures. In this regard, attention is directed to Lorcks et al who teach the use of biodegradable polymer mixtures having permeability to water vapor (breathable) containing at least one starch biopolymer and at least one polymer selected from the group consisting of aromatic polyesters, aliphatic-aromatic copolyesters, polyesteramide, etc. Lorcks et al's examples provide various compositions comprising a combination of soft and stiff

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thermoplastic biodegradable polymers having the claimed glass transition temperatures, e.g., blends comprising starch, polycaprolactone or aliphatic-aromatic copolyester as the soft component and polylactic acid or polyesteramide BAK 1095 as the stiff component. By virtue of their respiratory active, breathable and water resistant properties, Lorcks et al's biodegradable blends have utility in the same type of applications as do Schiffer et al's, e.g., personal care articles and medical articles. Accordingly, it would have been obvious to one having ordinary skill in the art to have employed a combination of stiff and soft thermoplastic biodegradable polymers having the claimed glass transition temperatures, as disclosed by Lorcks et al, as the biodegradable composition for Schiffer et al's filled monolayer with the reasonable expectation of success. This is particularly so since there is commonality in the types of biodegradable polymers disclosed by Schiffer et al and Lorcks et al.

With respect to the claims reciting a dead-fold property, it is reasonably believed that the particle filled-biodegradable compositions comprising a combination of stiff and soft thermoplastic biodegradable polymers described above would invariably possess dead-fold properties due to the presence of the particulate fillers which can comprise up to 80% by weight of the composition.

It is reasonably believed that at least some of the filler particles would protrude from the surface of the sheet due to the orientation process, which causes cavitation and localized separation between the polymer matrix and individual filler particles. Furthermore, the filler particles can have particle size diameters (up to about 10 microns) that are greater than the thickness of the sheet (about 5 microns).

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6. Claims 16-23 and 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0098341 A1 (Schiffer et al) in view of US 6,096,809 (Lorcks et al), described hereinabove.

In essence, the disclosure of Schiffer et al differs from claims 18 and 32 solely in its silence with respect to dead-fold properties or protrusion of filler particles. With respect to claim 18, it is reasonably believed that the particle filled-biodegradable compositions of Schiffer et al would invariably possess dead-fold properties due to the presence of the particulate fillers, which can comprise up to 80% by weight of the composition. As to claim 32, it is reasonably believed that at least some of the filler particles would protrude from the surface of the sheet (per claim 31) due to the orientation process, which causes cavitation and localized separation between the polymer matrix and individual filler particles. Furthermore, the filler particles can have particle size diameters (up to about 10 microns) that are greater than the thickness of the sheet (about 5 microns).

As to claim 16, attention is directed to Schiffer et al's figure 3 wherein the film is extruded into a pair of rollers which may be patterned so as to impart an embossed pattern to the film (page 4, paragraph 0039). Accordingly, it is within the scope of Schiffer et al's invention to produce a textured sheet, which would be expected to have non-planar nature and dead-fold properties due to the presence of the particulate fillers, which can comprise up to 80% by weight of the composition.

As to claims 29, 30 and 35, it would have been obvious to one having ordinary skill in the art to have employed a combination of stiff and soft thermoplastic biodegradable polymers having the claimed glass transition temperatures, as disclosed by Lorcks et al, as the

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biodegradable composition for Schiffer et al's filled monolayer with the reasonable expectation of success. This is particularly so since there is commonality in the types of biodegradable polymers disclosed by Schiffer et al and Lorcks et al.

7. Claims 1-15, 24-30, 34, 35 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,838,403 (Tsai et al) in view of US 6,096,809 (Lorcks et al), described hereinabove.

Tsai et al disclose biodegradable breathable monolayer films (and laminates therefrom) formed by mixing biodegradable polymers or mixtures thereof with a particulate filler, forming the mixture into a film, and stretching the film uniaxially or biaxially to cause voids to form around the filler particles. Suitable biodegradable polymers include polylactic acid, reading on the presently claimed stiff polymer, and other polymers such as polycaprolactone, copolyesters, etc., reading on the presently claimed soft polymer (columns 3-4). The filler particles constitute up to 70% by weight of the breathable film. The films have a water vapor transmission rate of at least about 1,000 g/m²/day, as required by present claim 12 (column 6, lines 30-35).

In essence, the disclosure of Tsai et al differs from the above-rejected claims in not expressly exemplifying a combination of stiff and soft thermoplastic biodegradable polymers having the claimed glass transition temperatures. In this regard, attention is directed to Lorcks et al who teach the use of biodegradable polymer mixtures having permeability to water vapor (breathable) containing at least one starch biopolymer and at least one polymer selected from the group consisting of aromatic polyesters, aliphatic-aromatic copolyesters, polyesteramide, etc. Lorcks et al's examples provide various compositions comprising a combination of soft and stiff thermoplastic biodegradable polymers having the claimed glass transition temperatures, e.g.,

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blends comprising starch, polycaprolactone or aliphatic-aromatic copolyester as the soft component and polylactic acid or polyesteramide BAK 1095 as the stiff component. By virtue of their respiratory active, breathable and water resistant properties, Lorcks et al's biodegradable blends have utility in the same type of applications as do Tsai et al's, e.g., personal care articles and medical articles. Accordingly, it would have been obvious to one having ordinary skill in the art to have employed a combination of stiff and soft thermoplastic biodegradable polymers having the claimed glass transition temperatures, as disclosed by Lorcks et al, as the biodegradable composition for Tsai et al's filled monolayer with the reasonable expectation of success. This is particularly so since there is commonality in the types of biodegradable polymers disclosed by Tsai et al and Lorcks et al.

With respect to the claims reciting a dead-fold property, it is reasonably believed that the particle filled-biodegradable compositions comprising a combination of stiff and soft thermoplastic biodegradable polymers described above would invariably possess dead-fold properties due to the presence of the particulate fillers which can comprise up to 70% by weight of the composition.

It is reasonably believed that at least some of the filler particles would protrude from the surface of the sheet due to the orientation process, which causes cavitation and localized separation between the polymer matrix and individual filler particles. Furthermore, the filler particles can have particle size diameters (up to about 50 microns).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

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Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-35 and 39-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Applications 10/087,256 and 11/103,999. Although the conflicting claims are not identical, they are not patentably distinct from each other because contain overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-35 and 39-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,572,340. Although the conflicting claims are not identical, they are not patentably distinct from each other because they contain overlapping subject matter.

Response to Arguments

11. Applicant's arguments filed April 6, 2005 have been fully considered and are persuasive to the extent that the rejection over WO 02/42365 to Wu et al has been withdrawn.

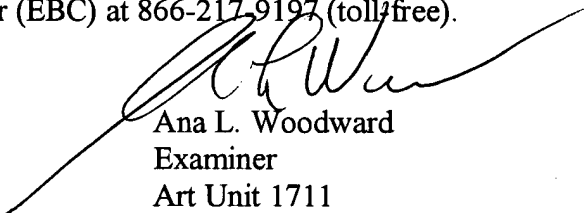
Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana L. Woodward whose telephone number is (571) 272-1082. The examiner can normally be reached on Monday-Friday (8:30-5:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).



Ana L. Woodward
Examiner
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